



Isagro USA, Inc.  
430 Davis Dr., Suite 240  
Morrisville, NC 27560

L0001786

**REGISTRATION ACTION:**

Adverse Effects Reporting-FIFRA 6(a)2

Fee Category: NA

Registration Fee: NA

15 May 2017

U.S. Environmental Protection Agency  
Document Processing Desk (6(a)2)  
Attn: Bob Miller  
One Potomac Yard  
2777 Crystal Drive  
Arlington, VA 22202

Subject: Adverse Effects Reporting- FIFRA 6(a)2; IR9804 (EPA Reg. No. 80289-23).

Dear Mr. Miller,

Under the FIFRA 6(a)2 requirements, Isagro S.p.A. d/b/a USA, Inc. (Isagro) is informing the Agency of an adverse effects data (new studies) for the Isagro product IR9804 containing the active ingredient Allyl isothiocyanate (EPA Reg. No. 80289-23).

Isagro generated new data to support California registration of the biochemical active ingredient Allyl isothiocyanate. During the preliminary review of the petition, California Department of Pesticide Regulation (DPR) Medical Toxicology Health Assessment Branch requested the registrant conduct additional data to support the petition. At this juncture, we are providing the Agency with a copy under the 6(a)2 reporting requirements.

The additional studies conducted and summarized in this letter are the following:

- 1) the Acute Neurotoxicity Study in the rat (OPPTS 870.6200),
- 2) the 90-Day Inhalation and Neurotoxicity Study in the Rat (OPPTS 870.3100, 870.3465 and 870.6200), and
- 3) the 2-Generation Study in the rat (OPPTS 870.3800).

Enclosed in the submission are the 8570-1 Application Form and Data Transmittal. Should you have any questions or comments pertaining to the Isagro IR9804 registration, please do not hesitate to contact me via e-mail at [jjanis@isagro-usa.com](mailto:jjanis@isagro-usa.com) or phone at 919-321-5203.

Sincerely,

Jonathan A. Janis  
Regulatory Manager

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Isagro USA, Inc.  
430 Davis Dr., Suite 240  
Morrisville, NC 27560

**REGISTRATION ACTION:**

Documentation Supporting the Registration

FEE CATEGORY: NA

REGISTRATION FEE: NA

**Regulatory Action in Support of which this Package is Submitted:**

Application to Support the Registration

**Product Names:** IR9804  
**EPA Registration Number:** 80289-23  
**Transmittal Date:** May 15, 2017

**Submitted Documents:**

Guideline Reference No.	Citation	MRID	Submitter	Status
870.6200	An Acute Inhalation Neurotoxicity Study of IR9804 in Sprague-Dawley Rats	50281501	Isagro S.p.A.	OWN
870.3800	An Oral (Gavage) Two-Generation Reproductive Toxicity Study of IR9804 in Rats	50281502	Isagro S.p.A.	OWN
870.3465, 870.3100, 870.6200	A 13-Week Whole Body Inhalation Combined Subchronic Neurotoxicity/Toxicity Study of IR9804 in Sprague Dawley Rats	50281503	Isagro S.p.A.	OWN

**Submitter:**

*Jonathan A. Janis*

Jonathan A. Janis  
Regulatory Manager

15 May 2017

Date

**Company Name:** Isagro USA, Inc.  
**Company Contact:** Jonathan A. Janis



# Receipt for Section 3

S: 1003643

Milestone Email: jjanis@isagro-usa.com

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: 6A2 Data

Fee For Service: ☐ Yes ☒ No

Company: 80289 ISAGRO S.P.A., D/B/A ISAGRO USA, INC.

V

Billable: ☐ Yes ☒ No

Print Letter

Enter More Information

Tracking

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 80289-23 Product Name: IR9804

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 15-May-2017

OPP Rec'd Date: 16-May-2017

Front End Date: 16-May-2017

Risk Manager Send Date: 16-May-2017

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Portal submission pkg. #19703. 6(a)(2) data.

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Receipt Content

Study

De

View/Edit





United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number Isagro S.p.A. (d/b/a USA, Inc.) / 80289-23	2. EPA Product Manager Bob Miller	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Isagro S.p.A. (d/b/a Isagro USA, Inc.) / IR9804	PM#	
5. Name and Address of Applicant (Include ZIP Code) Isagro-USA, Inc. 430 David Drive, Suite 240 Morrisville, NC 27560  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

Adverse effects reporting for Isagro S.p.A. (d/b/a USA, Inc.) (Company No. 80289) product IR9804 (EPA Reg. No. 80289-23). The submission includes new data for the active ingredient Allyl Isothiocyanate. For questions, please email me at [jjanis@isagro-usa.com](mailto:jjanis@isagro-usa.com).

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted					
If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)				
Name Jonathan A. Janis		Title Regulatory Manager		
		Telephone No. (Include Area Code) 919-321-5203		
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received  (Stamped)	
2. Signature <i>Jonathan A. Janis</i>		3. Title Regulatory Manager		
4. Typed Name Jonathan A. Janis		5. Date May 15, 2017		

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